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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,755	11/15/2001	Lawrence M. Boyd	4002-2729	8631

7590 09/15/2003

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EXAMINER

COMSTOCK, DAVID C

ART UNIT PAPER NUMBER

3732

DATE MAILED: 09/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/869,755	BOYD ET AL.	
	Examiner	Art Unit	
	David C. Comstock	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 November 2001 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

<ol style="list-style-type: none"> 1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,6</u>. 	<ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____.
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DETAILED ACTION

Specification

The specification is objected to because of the following informalities: page 13, line 19, "840" should be changed to --340--. Appropriate correction is required.

Claim Objections

Claims 27-37 are objected to because of the following informalities: claims 27-37 are misnumbered as claims "28-38" and should be changed to 27-37, respectively. In addition, the claim dependencies in each of these misnumbered claims should be amended accordingly. Appropriate correction is required. For examination purposes, the claims will be referred to using their correct numbering.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Alexander (2,519,811).

Alexander discloses a tool comprising a shaft 12 extending through a passageway of housing 17. An occlusion member 20 extends from the distal end of the housing. The occlusion member includes a plate that curves about the longitudinal axis

of the tool to conform to the shape of member 14. A fastener 16 is attached to the shaft. The plate has a groove 21 through which the fastener passes to allow the plate to slide relative to the housing. (See Figs. 1 and 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over McIntyre (4,950,296) in view of Brosnahan, III (5,645,598; cited by applicant).

McIntyre discloses a spacer 10 comprising an elongated body 12 and an opening into a chamber or hole 18 that extends perpendicularly to the longitudinal axis of the body (see Figs. 1 and 2 and col. 2, lines 47-52). The body defines two arms between the chamber and the two ends 14 and 16, respectively. The body is formed from the diaphysis of a long bone, i.e., the shaft of the femur (see col. 2, lines 53-58).

Osteogenic material 22 is packed into the spacer (see col. 2, lines 44-46; col. 2, line 61 - col. 3, line 4; and col. 3, line 28-36). McIntyre does not disclose the concave surfaces. Brosnahan discloses providing a fusion device 10 with concave surfaces 48,50 to allow the fusion device to be nested with another fusion device and allow the use of taller fusion devices for correct anatomical positioning (see Fig. 14 and col. 5, lines 55-62). It would have been obvious to one having ordinary skill in the art at the time the invention

was made to provide the spacer of McIntyre with concave surfaces, in view of Brosnahan, III, in order to allow the fusion device to be nested with another fusion device and allow the use of taller fusion devices for correct anatomical positioning. It is noted that positioning the concave surfaces such that they form concave ends on the arms would have been obvious since it has been held that mere relocation of features of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Brosnahan also discloses providing the fusion device with a tool engaging end 32 to allow the device to be inserted with a tool and to improve the convenience of the procedure (see col. 5, lines 8-12). It would have been further obvious to provide the spacer of McIntyre with a tool engaging portion, also in view of Brosnahan, III, in order to allow the spacer to be inserted with a tool and to improve the convenience of the procedure. With regard to claim 6, it is noted that the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. With regard to claim 7, it also would have been obvious to provide the spacer of McIntyre with threading, in view of Brosnahan, III, in order to prevent motion and provide secure attachment to the vertebrae (see Brosnahan, III, col. 4, lines 44-51). With regard to claims 11-14, it would have been further obvious to one having ordinary skill in the art at the time the invention was made to use recombinant human protein comprising BMP-2 or to use any of a number of known osteogenic materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David C. Comstock whose telephone number is (703) 308-8514.

DC

D.C. Comstock
05 September 2003



**EDUARDO C. ROBERT
PRIMARY EXAMINER**